REMARKS

I. STATUS OF THE CLAIMS

Claims 1-53 were pending at the time of the Action. Claims 20-53 have been withdrawn from consideration. Claim 1 has been amended. Support for the claim amendment can be found at lease in FIG. 1B. Claims 1-19 are under examination.

II. REJECTIONS UNDER 35 USC 112

Claim 13 is rejected as allegedly being indefinite in that the claim uses the term "derived." Applicants have clarified claims 13 that now reads: "The expression vector of claim 1, wherein said TSRE is a tissue specific regulatory element from an ARR2PB promoter, a probasin promoter, an osteocalcin promoter, a human kallikrein 2 promoter, a DD3 promoter, a Clara cell secretory protein promoter, a liver-type pyruvate kinase proximal promoter, an apoE promoter, an alcohol dehydrogenase 6 promoter, a MUC-1 promoter, a survivin promoter, a CCR5 promoter a PSA promoter, an APP promoter, an albumin promoter, or a telomerase promoter." In light of the currently pending claims the rejection is moot.

Claims 1-19 are rejected as allegedly failing to satisfy the written description requirement of 35 USC 112 because allegedly only one species of tissue specific regulatory elements is described. Applicants traverse.

MPEP §2163(I) states "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116." Given that the applicants describe using TSREs from the ARR2PB promoter, probasin promoter, osteocalcin promoter, human kallikrein 2 promoter, DD3 promoter, Clara cell secretory protein promoter,

liver-type pyruvate kinase proximal promoter, apoE promoter, alcohol dehydrogenase 6 promoter, MUC-1 promoter, survivin promoter, CCR5 promoter, PSA promoter, APP promoter, albumin promoter, and telomerase promoter, one of skill in the art will readily recognize the members of the tissue specific regulatory elements (TSREs) genus (Specification page 4-5 and 21-25). The fact that the one such TSRE was used to demonstrate that the particular combination of regulatory elements described in the current application provides a solution to certain problems associated with prior art expression vectors should not adversely effect the written description provided in the current specification. Furthermore, pages 21-25 of the specification describe examples of tissue specific/selective promoters. The specification states "[] the promoter need not be entirely specific for a given cell or tissue but, rather, should be active preferentially or selective in a particular cell type, for example a tumor cell." Specification at Page 21. Thus, Applicants have provided sufficient description of the tissue specific elements that reasonably conveys to one of skill that the inventors had possession of the claimed expression vector and that the invention was not limited to just ARR2PB promoter elements. Applicants respectfully request the withdrawal of the rejection.

III. REJECTIONS UNDER 35 USC 102 AND 103

Claims 1 and 5-19 are rejected under 35 USC 102 as allegedly being anticipated by Rubinchik et al. - an earlier publication co-authored by some of the current inventors. Applicants respectfully traverse.

Runbinchik *et al.* does not describe a first expression cassette having both a tissue specific regulatory element and transcriptional activating factor binding site for the transcriptional activating factor encoded by the first expression cassette. The first expression cassette described in the Rubinchik et al. reference comprises a tissue specific promoter driving expression of the tetracycline transactivator gene ("We have placed the tetracycline

transactivator gene under the control of a prostate-specific ARR2PB promoter..." Rubinchik et al. Abstract). There is no reference to a tetracycline-transactivator binding site or a tetracycline responsive element (TRE) in the expression cassette encoding the tetracycline transactivator. Thus, Rubinchik et al. does not teach all elements of the claimed invention.

The Action further rejects claims 1-19 under 35 USC 102/103 as being anticipated or obvious in view of US Patent publication 2004/0161847. Applicants traverse.

Phillips suffers from the same deficiency as does Rubinchik et al., the expression cassette encoding the transactivating factor does not contain a regulatory element that binds the transactivating factor. As diagramed in figure 1B, only the second expression cassette encoding the cardioprotective factor contains transactivator inducible elements. The expression cassette encoding the transactivating factor only comprises a cardiac promoter and not a transactivator inducible promoter. Applicants respectfully request withdrawal of the rejection.

The Examiner is invited to contact the undersigned attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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